

Annual Flash Report (unaudited)
Fiscal Year ended March 31, 2015

Supplemental Information

New Drugs in Development

as of May 12, 2015

In our ongoing effort to create products that will promote the health of more people worldwide, Ono has many new drug formulations under development, including the following main drugs:

Opalmon[®] Tablets (OP-1206 · α -CD)

Japan: J-NDA approved / thromboangitis obliterans, lumbar spinal canal stenosis (new formulation, co-development with Sumitomo Dainippon Pharma Co., Ltd.)

Onoact[®] Intravenous Infusion 150 mg (ONO-1101)

Japan: J-NDA approved / intraoperative tachyarrhythmia, post operative tachyarrhythmia under monitoring hemodynamics, tachyarrhythmia in low cardiac function (additional formulation)

Rivastach[®] Patch(ONO-2540 / ENA713D)

Japan: J-NDA filed / Alzheimer's disease (additional dosing regimen) (co-development with Novartis Pharma AG)

Proemend[®] Intravenous Infusion (ONO-7847 / MK-0517)

Japan: Phase III / chemotherapy-induced nausea and vomiting in pediatric patients (additional indication)

USA & Other Countries: Phase II / chemotherapy-induced nausea and vomiting in pediatric patients (additional indication) (Merck & Co., Inc.)

ONO-4164 / BMS-188667 (injection)

ONO-4164 is an intravenous preparation of Orenicia[®] and is marketed in Japan where it is indicated for use in patients of rheumatoid arthritis for whom other therapies have failed and overseas where it is indicated for use in patients with juvenile idiopathic arthritis.

Japan: Phase III / juvenile idiopathic arthritis (additional indication) (co-development with Bristol-Myers Squibb Company), Phase III / lupus nephritis (additional indication) (co-development with Bristol-Myers Squibb Company, being conducted as global clinical trial)

Overseas: Phase III / lupus nephritis (additional indication) (Bristol-Myers Squibb Company, being conducted as global clinical trial)

ONO-7057 / Carfilzomib (injection)

ONO-7057 is a proteasome inhibitor being developed for multiple myeloma, which is a cancer of plasma cells (one of blood cells). ONO-7057 is highly expected to be a new treatment option for multiple myeloma of which prognosis is considered poor.

Japan: Phase III / multiple myeloma

Overseas: Approved under Accelerated Drug Approval Program in US / multiple myeloma (launched in August 2012), Filed in Europe / multiple myeloma (Onyx Pharmaceuticals, Inc.)

ONO-5163 / AMG-416 (injection)

ONO-5163 is a calcium sensing receptor agonist currently being developed for the treatment of secondary hyperparathyroidism.

Japan: Phase III / secondary hyperparathyroidism

USA & Other Countries: Phase III / secondary hyperparathyroidism (Amgen Inc.)

Onoact[®] Intravenous Infusion 50mg/150 mg (ONO-1101)

Japan: Phase II/III / tachyarrhythmia in low cardiac function in pediatric patients (additional indication)

ONO-7643 / RC-1291 (tablet)

ONO-7643 is a small-molecule ghrelin mimetic being developed for cancer anorexia / cachexia. ONO-7643 has similar pharmacological actions to ghrelin, a circulating peptide hormone with multiple physiological actions, including appetite stimulation and muscle-building, and is therefore expected to be a breakthrough drug that improves quality of life (QOL) for patients impaired by a systemic wasting condition characterized by anorexia, lipolysis and muscle loss associated with the progression of cancer.

Japan: Phase II / cancer anorexia / cachexia

USA & Other Countries: Phase III / cancer anorexia / cachexia (Helsinn Healthcare, S.A.)

ONO-1162 (tablet)

ONO-1162 is an If channel blocker and is approved for the indication of chronic heart failure in addition to stable angina in Europe. It is under development in Japan for the indication of chronic heart failure.

Japan: Phase II / chronic heart failure

Overseas: Marketed / stable angina, chronic heart failure (Les Laboratoires Servier)

ONO-6950 (tablet)

ONO-6950 is a leukotriene receptor antagonist, and is under clinical development for bronchial asthma. It is expected to improve symptoms associated with the disease by inhibiting airway inflammation.

Japan: Phase II / bronchial asthma

USA: Phase II / bronchial asthma

ONO-7056 / Salirasib (tablet)

ONO-7056 is a Ras signal inhibitor which is expected to be effective in the cancers, such as pancreatic cancer, in which high RAS genetic mutation is found.

Japan: Phase I / solid tumor

USA: Phase I / pancreatic cancer (Kadmon Corporation, LLC), Phase II / non-small cell lung cancer (Kadmon Corporation, LLC)

ONO-7268MX1 / ONO-7268MX2 (injection)

ONO-7268MX1 and ONO-7268MX2 are peptide vaccines and are expected to have effects on cancers such as hepatocellular carcinoma.

Japan: Phase I / hepatocellular carcinoma

ONO-2160/CD (tablet)

ONO-2160 is a combination product with levodopa pro-drug and carbidopa which is currently developed for Parkinson's disease.

Japan: Phase I / Parkinson's disease

ONO-4053 (tablet)

ONO-4053 is a PGD2 receptor antagonist and is under clinical development for allergic rhinitis. It is expected to improve particularly nasal congestion, one of the three major symptoms of allergic rhinitis such as nasal congestion, sneezing and nasal discharge.

Japan: Phase II / allergic rhinitis

Europe: Phase II / allergic rhinitis

ONO-2370/Opicapone (tablet)

ONO-2370 is a long acting COMT inhibitor being developed for the treatment of Parkinson's disease. ONO-2370 is filed in Europe and the compound has shown a long-lasting effect on COMT inhibition from once daily dosing in clinical studies so far and is expected to improve a dosing convenience.

Japan: Phase I / Parkinson's disease

Europe: Filed / Parkinson's disease (BIAL)

ONO-4059 (capsule)

ONO-4059 is a Btk inhibitor being developed for the treatment of B cell lymphoma.

Japan: Phase I / B cell lymphoma

Europe: Phase I / B cell lymphoma

ONO-5371/ Metyrosine (capsule)

ONO-5371 is a tyrosine hydroxylase inhibitor against catecholamine biosynthesis, and is under clinical development for pheochromocytoma. ONO-5371 was approved and launched in the United States in 1979. In Japan, the Review Committee on Unapproved and Off-Label Drugs with High Medical Needs, set up by the Ministry of Health, Labour and Welfare (MHLW) regarded metyrosine as a drug with high medical needs and MHLW publicly sought pharmaceutical companies to develop metyrosine.

Japan: Phase I / pheochromocytoma

USA: Marketed / pheochromocytoma (Valeant Pharmaceuticals North America LLC)

ONO-2952 (tablet)

ONO-2952 is an antagonist of translocator protein (TSPO) that is involved in neurosteroid production mainly in central nervous system, and is under clinical development for irritable bowel syndrome. It is expected to improve various symptoms of the disease by blocking the mechanism eliciting abnormality of brain-gut interactions under stress.

USA: Phase II / IBS

ONO-9054 (eye drop)

ONO-9054 is a prostaglandin receptor (FP/EP3) agonist being developed for glaucoma and ocular hypertension.

USA: Phase II / glaucoma and ocular hypertension

ONO-8055 (tablet)

ONO-8055 is a prostaglandin receptor (EP2/EP3) agonist being developed for the treatment of underactive bladder.

Europe: Phase I / underactive bladder

ONO-1266 (capsule)

ONO-1266 is a sphingosine-1-phosphate receptor (S1P) antagonist being developed for the treatment of portal hypertension.

USA: Phase I /portal hypertension

ONO-4232 (injection)

ONO-4232 is a prostaglandin receptor (EP4) agonist being developed for the treatment of acute heart failure.

USA: Phase I /acute heart failure

ONO-4474 (capsule)

ONO-4474 is a tropomyosin receptor kinase (Trk) inhibitor being developed for the treatment of osteoarthritis.

Europe: Phase I /osteoarthritis

ONO-4538 / BMS-936558 (injection)

ONO-4538, a human anti-human PD-1 monoclonal antibody, is expected to be a potential treatment for cancer etc. PD-1 is one of the receptors expressed on activated lymphocytes, and is involved in the negative regulatory system to suppress the activated lymphocytes. It has been reported that tumor cells utilize this system to escape from the host immune responses. It is anticipated that blockade of the negative regulatory signal mediated by PD-1 will promote the host's immune response, in which tumor cells and viruses are recognized as foreign and eliminated. Further,

Japan:

Launched in September 2014 / melanoma,
J-NDA filed / non-small cell lung cancer,
Phase III / renal cell cancer (global clinical trial),
Phase III / head and neck cancer (global clinical trial),
Phase III / gastric cancer (global clinical trial),
Phase II / esophageal cancer
Phase II / Hodgkin's lymphoma
Phase I / hepatocellular carcinoma

Overseas:

USA / Launched in December 2014 / melanoma,
South Korea / Approved in March 2015 / melanoma,
Europe, Taiwan / Filed / melanoma,
USA / Approved in March 2015 / non-small cell lung cancer,
Europe, Taiwan / Filed / non-small cell lung cancer,
South Korea / Phase III / non-small cell lung cancer,
USA, Europe / Phase III / renal cell cancer,
USA, Europe, South Korea, Taiwan / Phase III / head and neck cancer,
USA, Europe / Phase III / glioblastoma,
South Korea, Taiwan / Phase III / gastric cancer,
USA, Europe / Phase II / diffuse large B cell lymphoma,
USA, Europe / Phase II / follicular lymphoma,
USA, Europe / Phase II / Hodgkin's lymphoma,
USA, Europe / Phase II / bladder cancer,

USA, Europe / Phase I/II / solid tumors (triple negative breast cancer, stomach cancer, pancreatic cancer, small cell lung cancer, bladder cancer),
USA, Europe / Phase I/II / colon cancer,
USA, Europe / Phase I / hepatocellular carcinoma,
USA, Europe / Phase I / hematological cancer, T-cell lymphoma, multiple myeloma, chronic leukemia, etc,
USA, Europe / Phase I / chronic myelocytic leukemia,
USA, Europe / Phase I / hepatitis C